

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : BATTISTA et al

Serial No. : NOT YET ASSIGNED

Art Unit: NOT YET ASSIGNED

Filed : September 5, 2003

Examiner: NOT YET ASSIGNED

For : HYDROXY ALKYL SUBSTITUTED 1,3,8-  
TRIAZASPIRO[4.5]DECAN-4-ONE DERIVATIVES USEFUL FOR  
THE TREATMENT OF ORL-1 RECEPTOR MEDIATED DISORDERS

I hereby certify that this correspondence is being deposited with the  
United States Postal Service as first class mail in an envelope addressed  
to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

September 5, 2003

(Date of Deposit)

Mary A. Appollina

(Name of applicant, assignee, or Registered Representative)

  
(Signature)

September 5, 2003

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e)  
(attached); or
- ☐ Please charge Deposit Account No. 10-  
0750/ / the fee of \$180.00 as set forth  
in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not

enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language. *A translation of JP 2000-169476 is attached.*


☐ The relevance of those listed references which are not in the English language is as follows: .

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/PRD-0039-USA-NP/MAA. This form is submitted in triplicate.

Respectfully submitted,

  
Mary A. Appollina  
Reg. No. 34,087  
Attorney for Applicants

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-3742  
DATED: September 5, 2003

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

|                               |                   |
|-------------------------------|-------------------|
| <b>Application Number</b>     | NOT YET ASSIGNED  |
| <b>Filing Date</b>            | SEPTEMBER 5, 2003 |
| <b>First Named Inventor</b>   | BATTISTA, et al   |
| <b>Group Art Unit</b>         | NOT YET ASSIGNED  |
| <b>Examiner Name</b>          | NOT YET ASSIGNED  |
| <b>Attorney Docket Number</b> | PRD-0039-USA-NP   |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. <sup>1</sup> | U.S. Patent Document |                                      | Name of Patentee or Applicant<br>of Cited Document | Date of Publication<br>of Cited Document<br>mm-dd-yyyy | Pages, Columns, Lines,<br>where relevant passages<br>or relevant figures appear |
|----------------------|--------------------------|----------------------|--------------------------------------|--|--|---|
|                      |                          | Number               | Kind Code <sup>2</sup><br>(if known) |  |  |   |
|                      |                          | 3,238,216            |                                      | Paul Adriaan Jan Janssen                           | 03-01-1966   |   |
|                      |                          | 3,839,340            |                                      | Scharpf  | 10-01-1974   |   |
|                      |                          | 4,329,353            | A                                    | Stokbroekx et al                                   | 05-11-1982   |   |
|                      |                          | 5,739,336            | A                                    | Weinhardt et al                                    | 04-14-1998   |   |
|                      |                          | 6,043,366            | A                                    | Adam et al   | 03-28-2000   |   |
|                      |                          | 6,060,482            | A                                    | Heine et al  | 05-09-2000   |   |
|                      |                          | 6,071,925            | A                                    | Adam et al   | 06-06-2000   |   |
|                      |                          | 6,262,066            | B1                                   | Tulshian et al                                     | 07-17-2001   |   |
|                      |                          | 6,277,991            | B1                                   | Hohlweg et al                                      | 08-21-2001   |   |
|                      |                          | 2003/0109539         | A1                                   | Jordan et al                                       | 06-12-2003   |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. <sup>1</sup> | Foreign Patent Document |                     |                        | Name of Patentee or<br>Applicant of Cited Document | Date of Publication<br>of Cited Document<br>mm-dd-yyyy | Pages, Columns, Lines,<br>where relevant<br>passages or relevant<br>figures appear | T <sup>6</sup> |
|----------------------|--------------------------|-------------------------|---------------------|------------------------|--|--|--|----------------|
|                      |                          | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup> |  |  |  |                |
|                      |                          | EP                      | 921,125             | ✓ B1                   | F. Hoffman-LaRoche AG                              | 06-09-1999   |  |                |
|                      |                          | EP                      | 997,464             | ✓ A1                   | Pfizer Inc.  | 05-03-2000   |  |                |
|                      |                          | JP                      | 2000-<br>169,476    | ✓                      | Banyu Pharmaceutical Co., Ltd.                     | 06-20-2000   |  | ✓              |
|                      |                          | WO                      | 93/12789            | ✓ A1                   | Beth Israel Hospital                               | 07-08-1993   |  |                |
|                      |                          | WO                      | 95/07294            | ✓ A1                   | Scios Nova Inc.                                    | 03-16-1995   |  |                |
|                      |                          | WO                      | 99/59997            | ✓ A1                   | Novo Nordisk A/S                                   | 11-25-1999   |  |                |
|                      |                          | WO                      | 00/06545            | ✓ A1                   | Schering Corporation                               | 02-10-2000   |  |                |
|                      |                          | WO                      | 01/07050            | ✓ A1                   | Schering Corporation                               | 02-01-2001   |  |                |
|                      |                          | WO                      | 01/36418            | ✓ A1                   | Novo Nordisk A/S                                   | 05-25-2001   |  |                |
|                      |                          | WO                      | 01/39723            | ✓ A2                   | Euroceltique, S.A.                                 | 06-07-2001   |  |                |
|                      |                          | WO                      | 01/94346            | ✓ A1                   | F. Hoffmann-LaRoche AG                             | 12-13-2001   |  |                |
|                      |                          | WO                      | 02/83673            | ✓ A1                   | Ortho-McNeil Pharmaceutical, Inc.                  | 10-24-2002   |  |                |

|                       |                    |
|-----------------------|--------------------|
| Examiner<br>Signature | Date<br>Considered |
|-----------------------|--------------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

|   |                               |                   |
|---|-------------------------------|-------------------|
| <b>Substitute for form 1449A/PTO</b><br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary)<br>Sheet 2 of 2 | <i>Application Number</i>     | NOT YET ASSIGNED  |
|   | <i>Filing Date</i>            | SEPTEMBER 5, 2003 |
|   | <i>First Named Inventor</i>   | BATTISTA et al    |
|   | <i>Group Art Unit</i>         | NOT YET ASSIGNED  |
|   | <i>Examiner Name</i>          | NOT YET ASSIGNED  |
|   | <i>Attorney Docket Number</i> | PRD-0039-USA-NP   |

[illegible]

|                       |                    |
|-----------------------|--------------------|
| Examiner<br>Signature | Date<br>Considered |
|-----------------------|--------------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450